



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 8, 2017

J. Austin Burns, Ph.D.
Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW
Suite 450 East
Washington, D.C. 20005

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation
Amendment – Add nematicide applications to the label, add an alternate brand name to the label, update an inert ingredient description on the basic confidential statement of formula (CSF), and make other changes to the label and basic CSF (including those requested by the EPA) (e.g., clarify the application rates)
Product Name: Actinovate STP Fungicide
EPA Registration Number: 524-643
Date of Applications: April 4, 2017
OPP Decision Numbers: 528593 and 528594

Dear Dr. Burns:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable. This non-PRIA amendment includes a change proposed in a labeling notification (OPP Decision No. 528594).

The alternate brand name Actinovate STP Fungicide / Nematicide has been added to the registration, and our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 10/05/2017

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may

distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Daniel Schoeff by phone at (703) 347-0143 or via email at schoeff.daniel@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized flourish at the end.

Jeannine Kausch, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

{Note to Reviewer: [bracketed text] is optional or alternate wording; {parenthetical text} denotes information for the reviewer.}

ACTINOVATE® STP FUNGICIDE

[ALTERNATE BRAND NAMES: ACTINOVATE® STP FUNGICIDE / NEMATICIDE,
ACTINOVATE® STP BIOLOGICAL FUNGICIDE, ACTINOGRO® ST]

FOR USE AS A DRY COATING OR COMMERCIAL [IN SLURRY] SEED TREATMENT
APPLICATION

ACTIVE INGREDIENT: (% w/w)

Streptomyces lydicus WYEC 108* 0.33%

OTHER INGREDIENTS 99.67%

TOTAL: 100.00%

* End-use product contains not less than 100 million (1×10^8) colony forming units per gram [cfu/g]
Streptomyces lydicus WYEC 108.

KEEP OUT OF REACH OF CHILDREN

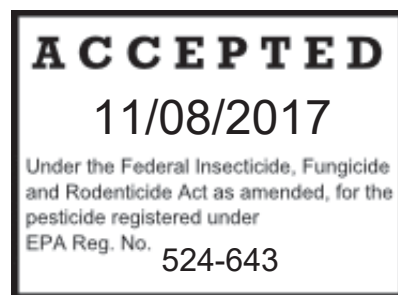
CAUTION

EPA Reg. No.: 524-643

EPA Est. {Enter appropriate EPA establishment no.}

Manufactured for:

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis MO 63167



For Medical, Transportation, Spill, or other Emergencies, Call Collect 24 Hours a Day
1-314-694-4000

[LOGO][BioAg logo][OMRI symbol/logo][Brand name][Tag-line]

Net Weight: {insert net weight}

[Batch code]

Not for sale or use after {expiry date} {Date stamped/placed on labeling will be six months after the date of manufacture}

[print plate number]

[Actinovate® and Actinogro® are Registered Trademarks of Monsanto Technology LLC]

{Note to Reviewer: [bracketed text] is optional or alternate wording; {parenthetical text} denotes information for the reviewer.}

See [booklet][panel][back panel][complete label] for additional precautionary statements, first aid, complete directions for use and warranty.

For product use information call: 1-877-775-8787

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of an emergency involving this product, or for medical assistance, call collect day or night: 1-314-694-4000.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Avoid contact with eyes, skin, or clothing. Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks

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Mixer/loaders and applicators must wear a NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Cover or collect seeds spilled during loading.

DIRECTIONS FOR USE

For use as a dry coating or commercial seed treatment application.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of four (4) hours.

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Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter treated area if there will be no contact with anything that has been treated.

PPE required for early entry into treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water) is:

- Coveralls
- Chemical-resistant gloves (made of any waterproof material)
- Shoes plus socks

Non-Agricultural Use Requirements

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses. Keep unprotected persons out of treatment area until seeds have dried or been packaged.

PRODUCT INFORMATION

[Insert brand name/This product] is a biological fungicide that, when applied to the seed, [protects][supports][guards] the seed and seedling against certain early season diseases caused by root rot and damping-off fungi. [Insert brand name/This product] is specially formulated to adhere to seeds as applied on farm, dry coating, or as a slurry. Protection is provided through [suppression][/][control] of soil borne fungi including *Fusarium*, *Rhizoctonia*, *Pythium*, *Phytophthora*, *Phymatotrichum omnivorum* (cotton root rot), *Aphanomyces*, *Monosporascus*, *Armillaria*, *Sclerotinia*, *Postia*, *Verticillium*, *Geotrichum*, and other root-decay fungi. The active ingredient in [Insert brand name/this product] colonizes the seed and root system protecting [guarding] them from harmful fungi.

In addition, [Insert brand name/this product] is also an effective biological nematicide providing [suppression][/][control] of pathogenic nematodes that attack the root system including Soybean Cyst (*Heterodera* spp.), Root-Knot (*Meloidogyne* spp.), and Lesion nematodes (*Pratylenchus* spp.), among others. The *Streptomyces lydicus* WYEC 108 in [Insert brand name/this product] produces metabolites that are destructive to the nematode egg, thereby reducing their population in the soil and root zone of plants.

INTEGRATED PEST MANAGEMENT (IPM)

Users may integrate [Insert brand name/this product] into an overall disease and nematode management strategy wherever the use of a fungicide or nematicide is necessary. [Insert brand name/This product] may be used in combination with compatible registered fungicide, insecticide, or nematicide seed treatments unless restricted.

APPLICATION DIRECTIONS

Compatibility:

[Insert brand name/This product] is compatible with many registered chemical fungicides, insecticides, nematicides, and fertilizers and can be [treater slurry][tank][seed hopper][dry] mixed with these substances, as appropriate, unless otherwise restricted. Consult manufacturer for compatibility questions and pre-check for compatibility as appropriate. Follow the most restrictive labeling limitations and precautions of all products used in mixtures.

{Note to Reviewer: [bracketed text] is optional or alternate wording; {parenthetical text} denotes information for the reviewer.}

Application Uses:

[Insert brand name/This product] is a dry biological product for use in seed coating applications in or on all raw agricultural commodities, food and fiber crops, and other agricultural production crops for the [suppression]/[control] of the following diseases: *Fusarium*, *Rhizoctonia*, *Pythium*, *Phytophthora*, *Phymatotrichum omnivorum* (cotton root rot), *Aphanomyces*, *Monosporascus*, *Armillaria*, *Sclerotinia*, *Postia*, *Verticillium*, *Geotrichum*, and other root-decay fungi. [Insert brand name/This product] can also be used for [suppressing]/[controlling] a range of economically damaging nematode pests: Soybean Cyst (*Heterodera* spp.), Root-Knot (*Meloidogyne* spp.), Lesion (*Pratylenchus* spp.), and others. High levels of nematode infestation may require other additional effective soil treatments as necessary.

Seed Treatment:

For use as a dry coating, on-farm application, or commercial seed treatment application.

Fungicide use

Applications to seed for fungal [suppression]/[control] may use commercial seed treater equipment (example: slurry, mist-type), dry-coating, and on-farm seed applications such as hopper-box or planter-box methods. Apply [insert brand name/this product] at a rate of 0.32 to 32.0 oz of [Insert brand name/this product] per cwt of seed. Refer to the tables below for specific use rates by crop.

Nematicide or nematicide + fungicide use

For applications to seed for nematode [suppression]/[control] or nematode + fungal [suppression]/[control], use only commercial seed treatment equipment [or dry coating methods]; do not use in hopper box, planter box, slurry box, or other on-farm seed treatment applications for nematode [suppression]/[control]. Apply [insert brand name/this product] [as a dry coating, or] using commercial seed treatment equipment (example: 'mist' type, slurry) at a rate of 0.32-0.64 oz (9-18 grams) of [insert brand name/this product] per cwt of seed. Refer to the table below for specific use rates by crop.

Preparation of the Slurry:

Fill [a] [slurry] [or] [mist-type] [or other] commercial seed treatment equipment tank with the required volume of water. Use between 16.9 fl oz and 33.8 fl oz of water per 220.5 lb of seed (between 500 mL and 1 L of water per 100 kg of seed). Pour the required amount of [Insert brand name/this product] onto the water surface. Wait until the product has disappeared in the water without stirring. Switch on the stirring system. Use the [slurry] [or] [equipment tank mixture] within 1 day of preparation. Uniform application of product to seed is necessary to ensure seed safety and best disease and/or nematode [protection][suppression][control]. Dilute with a sufficient amount of water to achieve uniform application to seed. Use high quality, properly cleaned seed.

For Pre-plant Seed Treatment:

Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seeds beyond planting time.

{Note to Reviewer: [bracketed text] is optional or alternate wording; {parenthetical text} denotes information for the reviewer.}

For Commercial Seed Treatment:

This product does not contain dye/colorant. All seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for humans or feed for animals.

Crops on which [Insert brand name/this product] may be used as a fungicide only:
[Insert brand name/This product] may be used in combination with other registered seed treatment fungicides, insecticides, or other registered pesticides where allowed. Pre-test for compatibility as appropriate with other seed treatment products.

CROP	SEED APPLICATION RATE FOR DRY COATING, ON-FARM, OR SLURRY
Wheat (Drill Box Application – Wheat only)	0.35-0.70 oz (9.8-19.6 grams) per cwt of seed
Alfalfa	1.8-3.7 oz (52-104 grams) per cwt of seed
Corn, Field	1-2 oz (28-56 grams) per cwt of seed
Corn, Silage	1-2 oz (28-56 grams) per cwt of seed
Corn, Sweet	1.76-3.5 oz (50-100 grams) per cwt of seed
Cotton	4-8 oz (112-224 grams) per cwt of seed
Peanuts	0.74-1.5 oz (21-42 grams) per cwt of seed
Popcorn	1.41-2.82 oz (40-80 grams) per cwt of seed
Sorghum	1-2 oz (28-56 grams) per cwt of seed
Soybeans	0.32-0.64 oz (9-18 grams) per cwt of seed
Sugar Beets	3.8-7.6 oz (107-214 grams) per cwt of seed
Sunflower	1.41-2.82 oz (40-80 grams) per cwt of seed

CROP	SEED APPLICATION RATE FOR DRY COATING, ON-FARM, OR SLURRY
Other Grain, Cereal; Other Oilseed; Other Vegetable, Legume: buckwheat; rye; millet; canola; safflower; snap and dry beans; succulent and dry peas; lentil; other cereal grains, oilseeds, and legume vegetables Other Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay): clover; vetch; trefoil	1-4 oz per cwt (0.25-1.00 grams per lb) of seed

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CROP	SEED APPLICATION RATE FOR DRY COATING, ON-FARM, OR SLURRY
Vegetable, Cucurbit: Cucumbers; melons; gourds; squash; cantaloupe; other cucurbit vegetables Vegetable, Fruiting except Cucurbits: Eggplant; sweet peppers; hot peppers; tomatoes; tomatillos; other fruiting vegetables Herbs, Spices, and Mints: Sage; rosemary; thyme; peppermint; dill; basil; oregano; other herbs, spices, and mints Vegetable, Leafy except <i>Brassica</i>: Celery; endive; lettuce; parsley; spinach; other leafy vegetables Vegetable, <i>Brassica</i> (Cole) Leafy: Broccoli; Brussels sprouts; cabbage; cauliflower; collards; kale; kohlrabi; mustard greens; other <i>Brassica</i> (cole) leafy vegetables Vegetable, Root and Tuber except Sugar Beet: White potatoes; sweet potatoes; carrot; ginger; ginseng; horseradish; turnip; beets; radish; other root and tuber vegetables Vegetable, Bulb: Garlic; onions; other bulb vegetables	4-32 oz per cwt (1-9 grams per lb) of seed

Crops on which [Insert brand name/this product] may be used as a nematicide or nematicide + fungicide:

CROP	SEED APPLICATION RATE FOR COMMERCIAL APPLICATION, including DRY COATING OR SLURRY
Soybeans	0.32-0.64 oz (9-18 grams) per cwt of seed

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TREATED SEED LABELING

The user is responsible for ensuring that the seed container meets all of the requirements under the Federal Seed Act. The Federal Seed Act requires that [bags][the container] of seed treated with [Insert brand name/this product] must be labeled with the following statements:

- This seed has been treated with [Insert brand name/this product][*Streptomyces lydicus* WYEC 108].
- Do not use treated seed for food, feed or oil production.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container away from feed and food. Store in a cool, dry place, between 40°F and 77°F. Do not store in direct sunlight and keep away from heat sources. Keep from overheating or freezing.

PESTICIDE DISPOSAL:

To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITS OF LIABILITY AND WARRANTY

Monsanto Company warrants that this product is reasonably fit for the purposes set forth in the DIRECTIONS FOR USE (“Directions”) when used in accordance with those Directions under the conditions described therein. This warranty is also subject to the inherent risks, conditions and limitations stated herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, INFRINGEMENT (ALONE OR IN COMBINATION WITH OTHER REGISTERED SEED TREATMENT PRODUCTS) OR MERCHANTABILITY IS MADE.

To the extent consistent with applicable law, buyer and all users are responsible for all loss or damage from use or handling of the product that results from conditions beyond the control of Monsanto Company, including, but not limited to, crop injury, ineffectiveness of such factors as weather conditions at planting, environmental conditions during seed storage, presence of other materials, seed of low quality or low vigor or low germination, or other unintended consequences that may result because of the manner of use or application inconsistent with that set for in the Directions.

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with Monsanto Company’s stewardship requirements and with Monsanto Company’s express written permission.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF MONSANTO COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF MONSANTO COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MONSANTO COMPANY OR ANY OTHER SELLER OF THE PRODUCT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES.

Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this LIMIT OF LIABILITY AND WARRANTY that may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

{Note to Reviewer: [bracketed text] is optional or alternate wording; {parenthetical text} denotes information for the reviewer.}

{Note: The following information will be affixed to the unit package}

ACTINOVATE® STP FUNGICIDE

**[ALTERNATE BRAND NAMES: ACTINOVATE® STP FUNGICIDE / NEMATICIDE,
ACTINOVATE® STP BIOLOGICAL FUNGICIDE, ACTINOGRO® ST]**

**FOR USE AS A DRY COATING OR COMMERCIAL [IN SLURRY] SEED TREATMENT
APPLICATION**

ACTIVE INGREDIENT: (% w/w)

Streptomyces lydicus WYEC 108* 0.33%

OTHER INGREDIENTS 99.67%

TOTAL: 100.00%

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KEEP OUT OF REACH OF CHILDREN

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EPA Est. {Enter appropriate EPA establishment no.}

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Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

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[LOGO][BioAg logo][OMRI symbol/logo][Brand name][Tag-line]

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If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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Applicators and other handlers must wear:

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- Long pants
- Shoes plus socks

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PESTICIDE DISPOSAL:

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CONTAINER HANDLING:

Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.